SNAS SLOVENSKÁ NÁRODNÁ AKREDITAČNÁ SLUŽBA

SLOVAK NATIONAL GLP COMPLIANCE MONITORING PROGRAMME

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Effective from: 01.05.2025	Edition: 7 Updating: 0	Document label: NP GLP

- **This document was created electronically -**

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By coming into force of this NP GLP expired the validity of NP GLP from 01.03.2022.

Content

1 INTRODUCTION

The National Good Laboratory Practice Compliance Monitoring Programme in the Slovak Republic (hereinafter NP GLP) was elaborated on the base of the Act No. 67/2010 Coll. on conditions applicable to the placing on the market of chemical substances and chemical mixtures, amending certain acts (Chemicals Act) and in compliance with the Government Decree No. 320/2010 Coll. in current version adjusting the activities of the test facilities and the activities of inspectors carrying out inspections, audits and verification of compliance with the principles of good laboratory by test facilities through inspections and audits of non-clinical studies on ensuring monitoring of GLP principles.

1.1 GLP PRINCIPLES

The legislative requirements concerning the regulation of chemicals in the Organisation for Economic Co-operation and Development (OECD) member states are based on the pro-active philosophy of preventing danger by testing of test items and assessing their potential risks.

GLP principles are related to testing of the health and environmental safety of the chemicals contained in pharmaceutical products, pesticides, cosmetic products, veterinary drugs and pharmaceuticals, food and feed additives and for the purpose of regulating industrial chemical substances and preparations, biocidal products, nanomaterials and from 2020 also for safety of medical products.

The Principles of GLP constitute the quality system relating to organizational processes and conditions under which non-clinical studies are planned, performed, monitored, recorded, archived and reported.

As a credible, shall be considered only the results of non-clinical studies which are performed by the holder of the GLP principles Certificate. Application of GLP when the studies are carried out ensures a quality and integrity of obtained data on assessment of health and environmental safety of new chemicals and enables the regulation bodies to trust these data when they are registered. Publishing of data about quality is very important from the international point of view. Regulation bodies of the countries can rely on safety data obtained in GLP test facilities abroad; in this way duplicity of tests and unnecessary repeated use of experimental animals can be avoided, allowing to reduce the time and financial means needed for registration.

1.2 GLP AND SLOVAK LEGISLATION HISTORY

GLP as a tool for quality management of laboratory and also field activities, by which the data on health and environmental safety of test items are obtained, in the frame of international conventions, is included among the requirements which should be in individual states regulated by their government or a central body of the civil service.

In the Slovak Republic, GLP system implementation is of paramount importance in export policy, for registration of regulated sphere products abroad and for licences granting.

The Slovak Republic, as one of preconditions to become an OECD member, had requirement to adopt into its legislation Council Act Decision [C (81)30/Final] (Decision of 12 May 1981 on the Mutual Acceptance of Data in the assessment of chemicals) and 1989 Council Decision Recommendation on Compliance with Principles of Good Laboratory Practice [C (89)87/Final] which ensured full implementation of the Council Decision of the year 1981.

The European Union membership bind the Slovak Republic to incorporate into its legislation the Directive of the Council 1999/11/EC on implementation of the GLP system and the Directive of the Council 1999/12/EC and their codified versions 2004/9/EC and 2004/10/EC. Mentioned Directives are concerning harmonization of monitoring procedures, establishing of national Monitoring Authority, system of inspections, monitoring and cooperation on an international level through the Commission for Technical Application of GLP at the Council of Europe and the GLP OECD Working Party.

The Slovak Republic implemented mentioned duties firstly by adopting the Act of the National Council of the Slovak Republic No.163/2001 Coll. on Chemical Substances and Chemical Preparations, the Act of the National Council of the Slovak Republic No. 140/1998 Coll. on Drugs and Medical Devices and by the Public Notice of the Ministry of Economy No. 65/2002 Coll. and No. 406/2002 Coll. on GLP Principles and their Observance, on Details on Granting and Withdrawal of GLP statement and Procedure of Monitoring of GLP Principles. Test Methods were listed in the Decree of the Ministry of Economy No. 2 / 2002, in Annex 5.

These Acts were amended by the Act No. 95/2007 Coll. and the Act No. 405/2008 Coll. by which was changed and amended the Act No. 163/2001 Coll. on Chemicals and Formulations as amended as well as by the Decree of the Slovak Government No. 298/2007 Coll. on Details on Test Facilities Performance, Job Descriptions of their Personnel and Details on Inspectors Performance and Job Descriptions of Inspectors Carrying out Inspections and Verifying GLP Principles. By this Decree was, at the same time, cancelled the Decree of the Ministry of Economy of the Slovak Republic No. 65/2002 Coll. as amended by the Decree of the Ministry of Economy of the Slovak Republic No. 406/2002 Coll.

In 2010, all those laws, regulations and ordinances related to GLP were repealed by the Act No. 67/2010 Coll. about conditions on chemical substances and mixtures for placing on the market and amending certain acts (Chemical Act) and by Government Regulation No. 320/2010 Coll. regulating the activities of test facilities and activities of inspectors carrying out inspections, audits and verification of compliance with the principles of good laboratory practice. It also stipulates the use of test methods specified in Council Regulation (EC) 440/2008 of 30ty May 2008 laying down test methods according to the European Parliament and Council Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). REACH is a European Union regulation adopted to improve the protection of human health and

the environment from the risks that chemicals can cause. It also supports alternative methods of assessing the hazards of substances in order to reduce the number of animal tests. The Regulation provides test methods for determining the intrinsic properties of substances (physical-chemical properties, toxicity and ecotoxicity) in accordance with Article 13, paragraph 3 of the REACH Regulation. Both Regulations are regularly actualised, therefore it is always necessary to follow the updated version available on Internet. Act No. 67/2010 Coll. repealed also Decree No. 2/2002 including Annex 5, indicating the test methods.

The Act 140/1998 Coll. on medicinal products and medical devices, as amended, which also states the obligations to carry out non-clinical studies in accordance with the requirements of GLP (§ 14 Toxico – pharmacological testing) was replaced by the Act on medicinal products and medical devices No. 362/2011 Coll. (§ 28 Toxico-pharmacological testing of human products and human medicines).

For other types of chemicals, directly binding EU Regulations and recommended Commission Recommendations are available at
https://ec.europa.eu/docsroom/documents/58794/attachments/1/translations/

In the year 2012 the Government Regulation No. 92/2012, which amends Regulation No 320/2010 Coll., was published in the Collection of laws of the Slovak Republic which regulates the activities of test facilities and activities of GLP inspectors and so the legislation of the Slovak Republic in the field of good laboratory practice is fully consistent with legislative EC and OECD.

1.3 GLP HISTORY IN SLOVAKIA

- **1981** – the first translation of FDA-GLP to Slovak language
- **1988** – Symposium "The GLP Principles for the control of medicinal products", which took place at Štrbské Pleso.
- **1990** – Drafted the document "Good Laboratory Practice for Non-clinical Laboratory Studies of New Drugs Research" as a background material for the Commission for new drugs of the Ministry of Healthcare of the Czech and Slovak Republic.
- **1991** – Authorization of the State Institute for Drug Control (SIDC) to perform a GLP state inspection body during the pre-clinical period of drug development, assessment of biological effects and harmlessness of new chemicals.

  On the basis of this authorisation the first certificate of GLP for the Research Institute of medicinal products in Modra was issued on 11. 11. 1991.
- **1994** – The first Questionnaire on implementation 1989 Council Decision Recommendation [C(89)87/Final] according to the requirements the OECD Secretariat was elaborated. The OECD Secretariat accepted the State Institute for Drug Control in Bratislava as a competent authority for GLP monitoring in the Slovak Republic in the field of safety testing of chemicals and pharmaceutical

preparations. Representatives of the Slovak Republic take part in the regular sessions of the GLP OECD Panel.

The State Institute for Drug Control as GLP Monitoring Authority in SR was incorporated in the OECD List of GLP monitoring authorities.

- **1995** – The Guidance of the Ministry of Healthcare of the Slovak Republic No. 12/1995 "Guidance on GLP Principles" was issued.

  The Slovak Republic was an observer in the GLP OECD Panel and the member of the expert group on the revision of the OECD Principles of Good Laboratory Practice.

  Monitored test facilities (GLP Certificate owners) were incorporated into the OECD database on the basis of yearly reviews of inspection activities.

- **1996** – An agreement on the need of inter-sectorial system of GLP Principles monitoring and supervision was reached among the representatives of the Slovak Office of Standards, Metrology and Testing, Ministry of Healthcare of the Slovak Republic, Ministry of Environment of the Slovak Republic, Ministry of Economy of the Slovak Republic and the State Institute for Drug Control.

- **1997** – The Chairman of the Slovak Office of Standards, Metrology and Testing set up the Technical Committee for the GLP. The second (updated) Questionnaire for OECD was drafted. The national monitoring programme and implementation level of 1989 Council Act [C (89)87/Final] was presented at the eighth session of the OECD GLP Work Group. Joining into the OECD pilot project "Mutual Joint Visit" for the assessment of implementation of 1989 Council Act and national monitoring authority's procedures, under the terms of mutual data recognition.

- **1998** – Establishing of the Slovak National Accreditation Service based on the decision of Chairman of the Slovak Office of Standards, Metrology and Testing of the Slovak Republic No. 4/1997 (in past from 1993 named Slovak National Accreditation System).

  A Slovak official representative in the OECD GLP Working Group was elected as a first vice-chairman of the SNAS Accreditation Commission.

  An OECD international inspection group verified implementation of the 1989 Council Act in the frame of the Pilot Project "Mutual Joint Visits". In the report was mentioned the only one non-compliance: in the Slovak legislation were not fully implemented requirements of the Council Decision Recommendation on Compliance with Principles of Good Laboratory Practise [C (89)87/Final]. Other procedures related to the national monitoring authority, inspection procedures and monitoring were fully accepted.

  International recognition of the GLP statement issued in the Slovak Republic is the final result of this inspection.

  The participation of the representative of Slovakia on the on-site visit OECD in Norway.

- **1999** – Establishing of the Slovak National Accreditation Service (SNAS) as the government subsidized organization with a legal identity (Act No. 264/1999 Coll.); after its reorganization the GLP Department continues to operate in GLP activities.
- **2000** – The adoption of the Slovak Republic to OECD (on December 14th, 2000, as the 30rd Member State).
- **2001 –** The GLP principles enacted by the Act of the National Council of the Slovak Republic No. 63/2001 Coll. on Chemicals and Chemical Formulations.
- **2002 –** A Public Notice of the Ministry of Economy of the Slovak Republic No. 65/2002 Coll. on Details of the GLP Procedure Verifying and Observing, on Details on Issuing and Withdrawing of the GLP Statement and on GLP Monitoring Procedure.
- **2003 –** Follow-up Mutual Joint Visit, it was stated that the Slovak Republic fully implemented the Council Decision Recommendation on Compliance with Principles of GLP [C (89)87/Final].
- **2004** – Adoption of Slovakia as the member of European Union (May 1st,2004)
- **2004 – 2006 –** Preparation of the Government Decree on GLP Principles (codified Directives 2004/9/EC and 2004/10/EC were taken).

  Amendment to the Act on Chemical Substances and Chemical Preparations was negotiated in the National Council of the Slovak Republic.
- **2007 –** The Act No. 95/2007 Coll. was adopted which amends the Act No. 163/2001 Coll. on Chemical Substances and Chemical Preparations as amended.

  The Decree of the Slovak Government No. 298/2007 Coll. was issued stipulating details on test facilities performance, job descriptions of its personnel, job descriptions and activities of inspectors carrying out inspections and verifications of GLP principles.
- **2008** – National GLP Compliance Programme in the Slovak Republic was drafted and published.

  The Act No. 405/2008 Coll. was adopted amending the Act No. 163/2001 Coll. on Chemical Substances and Chemical Preparations as amended.
- **2009** – Updating of the National Programme for compliance with the principles of GLP in Slovakia, publishing of the English version on the SNAS website.
- **2010** – Issuing of Act 67/2010 Coll. about conditions for supplying of chemical substances and mixtures on the market and amending certain acts (Chemical Act) and Government Regulation 320/2010 Coll. regulating the activities of test facilities and activities of inspectors carrying out inspections, audits and verification of compliance with the principles of good laboratory practice.

- **2011** – Updating of the National Programme for compliance with the Principles of GLP in accordance with the new legislation.

  In cooperation with the Legislative Department of Ministry of economy work on elimination of mistakes in the Government regulation No. 320/2010 Coll., which regulates the activities of test facilities and the activities of inspectors carrying out inspections, audits and verification of compliance with the principles of GLP.

  The participation of the representative of Slovakia on the on-site visit OECD in South Korea.

- **2012** – Nomination of the representative of the Ministry of Environment SR to the Committee SNAS for GLP.

  Update of the NP GLP on the basis of Decree No 92/2012 Coll., which amends the regulation of the Government of the Slovak Republic No. 320/2010 Coll. regulating the activities of test facilities and activities of inspectors carrying out inspections, audits and verification of compliance with the principles of good laboratory practice.

- **2013** – Nomination of the representative of the Ministry of Economy SR to the Committee SNAS for GLP.

- **2014** – Nomination of the representative of the Ministry of Agriculture and Rural Development SR to the Committee SNAS for GLP, update of NP GLP on the basis of organisational changes in SNAS.

- **2015** – on-site visit OECD on GLP compliance by representatives from The Netherlands and New Zealand nominated by WG GLP OECD in Slovakia, with conclusion – no non-compliances founded in activities of National GLP Compliance monitoring Authority.

- **2016** – Report from on-site visit was evaluated by all member states during 30th WG GLP OECD in Nice with conclusion, that Slovakia (represented SNAS as GLP Monitoring Authority) fulfils all requirements for mutual acceptance of data (MAD) and results of test facilities included in Monitoring programme of Slovak Republic will continue to be accepted in MAD frame.

  The introduction of the electronic accreditation information system (AIS) in SNAS work, electronic communication with entities in carrying out inspections.

- **2018** – update of NP, the change of the inspection cycle to a two-year period, in line with most OECD countries.

  The participation of the representative of Slovakia on the on-site visit (OSE) OECD in Germany.

- **2023** – participation of a representative of Slovakia in the OECD international on-site evaluation (OSE) in Belgium and Ireland.

- **2025** – Planned evaluation of SNAS in the field of good laboratory practice (on-site visit OECD by delegated representatives of the OECD WP GLP from Poland and Mexico).

1.4 ACTIVITIES ABROAD FOR COUNTRIES WITHOUT OWN NATIONAL MONITORING AUTHORITY ACCEPTED IN MAD OECD

Test facilities are included in National GLP compliance Monitoring Program of Slovak Republic and have granted GLP Certificates issued by SNAS to the time when own national monitoring authority fulfilled all criteria and is accepted in MAD

2001 – 2011	Poland
2003 – 2006	India
2010 – still lasts	Ukraine
2012 – 2023	The Russian Federation

(cooperation ended after the expiration of the validity period of the issued SLP certificates - sanctions due to the war in Ukraine)

2016 – still lasts	Serbia
2017 – still lasts	Kazakhstan

2 DEFINITIONS OF TERMS AND ABBREVIATIONS

From OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, No.1, OECD Principles of Good Laboratory Practice (as revised in 1997), placed in the same order as in the original document.

2.1 GLP

Good Laboratory Practice (GLP) – a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. Non-clinical studies are performed in test facilities, which are laboratories, greenhouses and fields.

National GLP Compliance monitoring programme (NP GLP) – inspects if test facilities implemented GLP principles to practice and if they are able to ensure that the resulting data are of adequate quality. NP GLP defines the scope and coverage of the programme, provides information on the mechanisms through which the test facility enters to the program, about the types of inspections and study audits, describes the different types of inspections as well as their frequency, and defines the powers of inspectors.

GLP Certificate - the document declares that the test facility (laboratory) performs studies (tests) in compliance with GLP Principles.

National Monitoring Authority in OECD and EC documents = Accreditation Body (SNAS) in GLP legislation in Slovakia.

2.2 TERMS CONCERNING THE ORGANISATION OF A TEST FACILITY

Test facility - the persons, premises and operational unit(s) that are necessary for conducting the non-clinical health and environmental safety study. For multi-site studies, those which are conducted at more than one site, the test facility comprises the site at which the Study Director is located and all individual test sites, which individually or collectively can be considered to be test facilities.

Test site - means the location(s) at which a phase(s) of a study is conducted.

Test facility management- the person(s) who has the authority and formal responsibility for the organisation and functioning of the test facility according to these Principles of Good Laboratory Practice. Implements legal acts, administrative-legal actions in all matters relating to the test facility on the basis of the Treaty on the establishment of a test facility or by law.

Test site management(if appointed) - the person(s) responsible for ensuring that the phase(s) of the study, for which he is responsible, are conducted according to these Principles of Good Laboratory Practice.

Head of test facility – in case of more complicated organisation structure, person which is directly responsible for performing activities in test facility according GLP (Director of Department, Head of laboratory...). Powers to ensure the activities according to the principles of GLP were to him delegated by the management of the test facility or defined in his job description.

Sponsor - an entity which commissions, supports and/or submits a non-clinical health and environmental safety study to Regulation Authority.

(See also Government Regulation No. 320/2010 Coll., § 3, (5)).

Note

Sponsor may be:

- Subject that proposes to conduct and supports, by providing financial or other resources, non-clinical health and environmental safety studies;*

- Subject that submits non-clinical health and environmental safety studies to the competent authority for product registration or other application for which compliance with the principles of GLP is required.*

** A "subject" may be an individual, a company, an association, a scientific or academic institute, a government agency or their organizational units, or any other legally identifiable entity.*

Study Director - the individual responsible for the overall conduct of the nonclinical health and environmental safety study, including the study plan and the final report.

Principal Investigator - an individual who, for a multi-site study, acts on behalf of the Study Director and has defined responsibility for delegated phases of the study.

Quality Assurance Programme (QAP) - a defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with these Principles of Good Laboratory Practice.

Quality Assurance (QA) – resources responsible for implementing and maintaining the QAP.

Note: QA responsibilities in GLP do not include, but are not limited to, managing quality system documentation, managing organizational process improvement tools (although some test facilities may assign these activities to QA), approving deviations, or approving resource adequacy. It is recognized that other quality systems (e.g., ISO 9000, Good Manufacturing Practice (GMP), ISO 17025) use the term "quality assurance" in different contexts.

Standard Operating Procedures (SOP) - documented procedures which describe how to perform tests or activities normally not specified in detail in study plans or in official and generally accepted test methods (OECD, REACH).

Master Schedule - a compilation of information to assist in the assessment of workload and for the tracking of studies at a test facility.

2.3 TERMS CONCERNING THE NON-CLINICAL HEALTH AND ENVIRONMENTAL SAFETY STUDY

Non-clinical health and environmental safety study – henceforth referred to simply as "study", means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.

Short-term study – a study of short duration with widely used, routine techniques.

Multi-site study – means any study that has phases conducted at more than one site. Multi-site studies become necessary if there is a need to use sites that are geographically remote, organisationally distinct or otherwise separated. This could include a department of an organisation acting as a test site when another department of the same organisation acts as the test facility.

Study phase – defined activity or set of activities in the conduct of a study.

Study plan – a document which defines the objectives and experimental design for the conduct of the study, and includes any amendments.

Study plan amendment – an intended change to the study plan after the study initiation date.

Study plan deviation – an unintended change from the study plan after the study initiation date.

Test system – any biological, chemical or physical system or a combination thereof used in a study.

Raw data – all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information.

Specimen – any material derived from a test system for examination, analysis, or retention.

Study initiation date – the date the Study Director signs the study plan.

Experimental starting date – the date on which the first study specific data are collected.

Experimental completion date – the last date on which data are collected from the study.

Study completion date – the date the Study Director signs the final report.

2.4 TERMS CONCERNING THE TEST ITEM

Test item – an article that is the subject of a study. The conclusion of a GLP study provides information on the properties of the test item which allows an assessment of the risk it presents to the safety of humans, animals or the environment. It should be noted that test item is also referred to as "test chemical" in some of the OECD Test Guidelines.

Terminology in OECD Test Guidelines to designate what is tested. In June 2013, OECD's Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology agreed that where possible with respect to Test Guidelines, a more consistent use of the term "test chemical" describing what is being tested should now be applied in new and updated Test Guidelines. However, it is important to note that previously adopted OECD Test Guidelines will still use the terms "test item", "test compound", "test substance" or other similar term to describe what is being tested." The intention of this proposal is not to provide a new definition of the term "chemical(s)", but rather to be consistent with the UN definition of it when applicable, i.e. in Test Guidelines that make reference to the UN GHS for Classification and Labelling where "chemical" means "substance and mixture".

Reference item("control item") – any article used to provide a basis for comparison with the test item.

Batch – a specific quantity or lot of a test item or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.

Vehicle – any agent which serves as a carrier used to mix, disperse, or solubilise the test item or reference item to facilitate the administration/application to the test system.

Formulation (or mixture) - a combination of a test item and different ingredients such as excipients that are combined and administered and/or applied to the test system in a different form, e.g. tablet, capsule, solution.

Preparation of test item (or prepared test item) – could be a formulation (or mixture) containing the test item or the test item in a vehicle, where the combination is obtained by dilution, mixing, dispersion, suspension, solubilisation and/or another process with the intention to be administered to the test system. The test facility can be supplied with the test item or with preparation(s) of the test item to be processed again or preparation(s) of the test item ready to be applied or administrated to the test system (also called "ready-touse").

A test item which is encapsulated or packed in some other way, in the absence of excipients or a vehicle, for the purposes of delivery to the test system is not regarded as a prepared test item in this document.

Characterisation – determines attributes of the test item and provides the evidence to support its suitability for use in GLP studies.

Identification – the process of checking and assessing the test item against the supplied information to determine whether the test item is as expected. Supplied information could be the shipping documents, emails from the supplier, the test item label, etc. Typical characteristics used to identify the test item would be the name, batch number, purity, concentration, composition, chemical, physical and biological parameters. Identification can also include a physical and/or analytical check. The process of identification should be carried out prior to the start of the experimental phase of a GLP study

Expiry Date (or Expiration Date) – the designated date a test item is expected to remain within established shelf-life specifications if stored under defined conditions and after which it should not be used.

Retest Date – the date a test item should be re-examined to ensure that it is still suitable for use.

2.5 TERMS CONCERNING TEST FACILITY INSPECTION

Test Facility Inspection – an on-site examination of the test facility's procedures and practices to assess the degree of compliance with GLP Principles. During inspections, the management structures and operational procedures of the test facility are examined, key technical personnel are interviewed, and the quality and integrity of data generated by the facility are assessed and reported to ensure that the resulting data are of adequate quality for assessment and decision-making by national regulation authority.

Inspector – a person who performs the test facility inspections and study audits on behalf of the (National) GLP Monitoring Authority (SNAS).

Lead Inspector – experienced inspector (named after fulfilling of defined requirements, see p. 18), is the head of the inspection team, leads and coordinates the conduct of inspections, is responsible for elaboration of Summary Report from inspection.

Study Audit – a comparison of raw data and associated records with the interim or final report in order to determine whether the raw data have been accurately reported, to determine whether testing was carried out in accordance with the study plan and Standard Operating Procedures, to obtain additional information not provided in the report, and to establish whether practices were employed in the development of data that would impair their validity.

Report from inspection – official document in writing on completed inspection where all assessed elements and activities are identified and namely all drawbacks are mentioned and the measure of GLP principles observances is assessed. It determines data quality and integrity of the monitored test facility.

Remote inspection – inspection carried out without being present on site, using electronic means of communication.

3 ABBREVIATIONS

AIS	Accreditation Information System
EC	European Commission
EU	European Union
GLP	Good Laboratory Practise
I	Inspector
IG	Inspection Group
LI	Lead Inspector
MAD	Mutual Acceptance of Data
MH SR	Ministry of Economy of the Slovak Republic
MPRV SR	Ministry of Agriculture and rural development of the Slovak Republic
MSA	Methodological Guideline (for Accreditation – Slovak version)
MSA G	Methodological Guideline for Good Laboratory Practise
MZ SR	Ministry of Healthcare of the Slovak Republic
MŽP SR	Ministry of environment of the Slovak Republic
NP	National Programme (GLP)
OECD	Organisation for Economic Cooperation and Development
OG	GLP Guarantor – (in SNAS person responsible for GLP)
QAP	Quality Assurance Programme
QAU	Quality Assurance Unit
REACH	Registration, Evaluation, Authorization of Chemicals
RD	Controlled documentation
SNAS	Slovak National Accreditation Service
SN GLP CMP	Slovak National GLP Compliance Programme
SOP	Standard Operating Procedure

SR	Slovak Republic
ŠÚKL	State Institute for Drug Control (ŠÚKL in Slovak)
ÚNMS	Slovak Office of Standards, Metrology and Testing (ÚNMS in Slovak)
TL	Form (controlled documentation)
V-SLP	SNAS Committee for Good Laboratory Practise
ÚPVS	Central Government Portal (ÚPVS in Slovak)
WG	Working Group

4 RELATED DOCUMENTS SR

Act No. 67/2010 Coll. on the conditions for supplying of chemical substances and mixtures on the market and amending certain acts (Chemical Act)

Government Regulation 320/2010 Coll. regulating the activities of test facilities and activities of inspectors carrying out inspections, audits and verification of compliance with the principles of good laboratory practice.

Government Regulation 92/2012 which amends Government Regulation 320/2010 Coll. regulating the activities of test facilities and activities of inspectors carrying out inspections, audits and verification of compliance with the principles of good laboratory practice.

Act No. 53/2023 Coll. on the accreditation of conformity assessment bodies

ST-07	SNAS Committee for GLP (Creation, status and activity)
ST-08	The Commission on appointment of SNAS Assessors
RR-02	Price list of SNAS services
RR-03	The principles for determining the amount of the remuneration for the services provided for SNAS
IP-05	Safety of information in electronic form and instructions for users of workstations
IP-10	The register of SNAS assessors, inspectors and experts

4.1 METHODICAL GUIDELINES SNAS:

MSA series G – all MSAs issued by SNAS, related to GLP available on the website www.snas.sk

MSA G-01	General Requirements for Preparation of Good Laboratory Practise Documents
MSA G-02	Procedures for GLP Inspection
MSA G-03	Laboratory Inspections and Study Audits
MSA G-05	Compliance of Laboratory Suppliers with GLP Principles
MSA G-06	The Application GLP Principles to Field Studies

MSA G-07 The Application of GLP Principles to Short-term Studies
MSA G-08 The Role and Responsibilities of the Study Director in the GLP Studies
MSA G-09 Guidance for the Conduct of Laboratory Inspections and Study Audits
MSA G-10 The Application of the Principles of GLP to Computerised Systems
MSA G-11 The Role and Responsibilities of the Sponsor in the Application of Principles of GLP
MSA G-12 Requesting and Carrying out Inspections and Study Audits in Another Country
MSA G-13 The Application of the Principles of GLP to the Organisation and Management of Multi-site Studies
MSA G-14 The Application of the Principles of GLP to in Vitro Studies
MSA G-15 Establishment and Monitoring of Archives that Operate in Compliance with the Principles of GLP
MSA G-16 Guidance on the GLP Requirements for Peer Review of Histopathology
MSA G-17 Application of GLP Principles to Computerised Systems
MSA G-17A GLP and Cloud Computing
MSA G-18 OECD Position Paper Regarding the Relationship between the OECD Principles of GLP and ISO/IEC 17025
MSA G-19 Management, characterisation and usage of test items
MSA G-20 Guidance Document for Receiving Authorities on the Review of the GLP Status of Non-Clinical Safety Studies
MSA G-21 OECD Position Paper Regarding Possible Influence of Sponsors on Conclusions of GLP Studies
MSA G-22 GLP – Data Integrity
MSA G-23 Quality Assurance and GLP
MSA G-24 Quality Improvement Tools and GLP
MSA G-25 Good Laboratory Practice and IT Security

5 RELATED DOCUMENTS EÚ

Directive 2004/10/EC of the European Parliament and the Council on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemicals substances.

Directive 2004/9/EC on the inspection and verification of GLP (Codified version).

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and about establishing of European Chemicals Agency as amended.

Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP) as amended.

Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals **(REACH).**

5.1 OECD

1981 Council Act Decision [C (81)30/Final] on the Mutual Acceptance of Data in the Assessment of Chemicals,

1989 Council Decision Recommendation on Compliance with Principles of Good Laboratory Practice [C (89)87/Final]

1998 Council Decision amending Annex II. to the Council Decision [C (81)30/Final]

5.2 OECD DOKUMENS - OECD PRINCIPLES OF GLP - GUIDELINES

No. 1 OECD Principles on Good Laboratory Practice (as revised in 1997)

Guidance Documents for Compliance Monitoring Authorities

No. 2 Revised Guides for Compliance Monitoring Procedures for GLP (1995)
No. 3 Revised Guidance for the Conduct of Laboratory Inspections and Study Audit (1995)
No. 9 Guidance for the Preparation of GLP Inspection Reports (1995)

GLP Consensus Documents

No. 5 Compliance of Laboratory Suppliers with GLP Principles (as revised in 1999)
No. 6 The Application of the GLP Principles to Field Studies (as revised in 1999)
No. 7 The Application of the GLP Principles to Short-Term Studies (as revised in 1999)
No. 8 The Role and Responsibilities of the Study Director in GLP Studies (as revised in 1999)
No. 13 The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies (2002)

Advisory Documents of the Working Group on GLP

No. 11 The Role and Responsibility of the Sponsor in the Application of the Principles of GLP (1998)
No. 12 Requesting and Carrying Out Inspections and Study Audits in another Country (2000)

No. 14 The Application of the Principles of GLP to in vitro Studies (2004)
No. 15 Establishment and Control of Archives that Operate in Compliance with the Principles of GLP (2007)
No. 16 Guidance on the GLP Requirements for Peer Review of Histopathology (2014)
No. 17 Application of GLP Principles to Computerised Systems (2016)
No. 19 Management, Characterisation and Use of Test Items (2018)
No.22 GLP – Data Integrity (2021)
No. 23 Quality Assurance and GLP, second edition (2022)

Position Papers

No. 18 OECD Position Paper Regarding the Relationship between the OECD Principles of GLP and ISO/IEC 17025 (2016)
No. 21 OECD Position Paper Regarding Possible Influence of Sponsors on Conclusions of GLP Studies (2020)
No. 24 OECD Position Paper on Quality Improvement Tools and GLP (2022)
No. 25 OECD Position Paper on Good Laboratory Practice and IT (2024)

Guidance for Receiving Authorities

No. 20 Guidance Document for Receiving Authorities on the Review of the GLP Status of Non-Clinical Safety Studies (2019)

6 FACTUAL PART OF NP GLP

6.1 GENERAL INFORMATION

In Slovakia, there exists the only one monitoring body, responsible for monitoring GLP principles by test facilities – Slovak National Accreditation Service. This activity is provided by specialist – GLP Guarantor and external inspectors. GLP Guarantor is also representative of Slovakia in the Working Party for GLP OECD, Working Group for GLP EC and EMA.

Address: Slovak National Accreditation Service (SNAS)
Karloveská 63
P.O. Box 74
840 00 Bratislava 4
website and contacts: https://www.snas.sk/en

6.1.1 SNAS performance in the area of GLP

In the Slovak Republic, an agreement was reached in 1996 between the departments of the Ministry of Health of the Slovak Republic, the Ministry of Environment of the Slovak Republic, the Ministry of Agriculture and Rural Development of the Slovak Republic,

the Ministry of Economy of the Slovak Republic and Slovak Office of Standards, Metrology and Testing on the need for a unified, supra-departmental monitoring of the conditions for compliance with the GLP Principles. On 1 July 1997, the Chairman of the Slovak Office of Standards, Metrology and Testing established the Committee for Good Laboratory Practice at the State Institute for Drug Control in Bratislava and, after the transformation of SNAS into a state-subsidized organization (pursuant to Section 22 of Act No. 264/1999 Coll., as amended, where the Ministry of Economy of the Slovak Republic authorized SNAS as the sole accrediting legal entity to carry out accreditation in the Slovak Republic), it continued its activities as the Department of Good Laboratory Practice of SNAS. Since 2013, the GLP area has been included in the "Department of Laboratories, Inspection Bodies and GLP (OLIS)" within the organizational structure of SNAS.

The activity of SNAS in the field of GLP was enshrined in Act no. 505/2009 Coll. on the accreditation of conformity assessment bodies and on the amendment of certain laws in § 9 "Position and scope of the Slovak National Accreditation Service" defined in letter k) that SNAS carries out inspection and verification of testing facilities in the area of compliance with the principles of good laboratory practice according to special regulations.

In the currently valid Act on Accreditation No. 53/2023 Coll. good laboratory practice was included in §3 point (7), letter j) – which states that SNAS "carries out the activities of the accrediting person according to the Chemical Act".

This activity includes, inter alia:

- Nomination of inspection group (consisting of inspectors who are appropriate technically knowledgeable, experienced and qualified for assessment of given test facility and if necessary, based on a contract a qualified expert should be incorporated into the group) for inspection of test facility and/or study audit;
- to conduct inspections of test facilities and audit of studies in order to assess whether they comply with GLP Principles (also on the request of any Regulatory Authority);
- to issue Certificates on GLP principles (hereinafter Certificate);
- to assess, on request, GLP principles also abroad; it should be previously negotiated with pertinent national accreditation body or other competent body in relevant country, if exists;
- to publish current list of test facilities with a valid certificate on the SNAS website and in the Slovak Office of Standards, Metrology and Testing Newsletter.
- once a year, a list of performed inspections of test facilities and a plan of inspections for the following year is sent to the OECD and EC Secretariat;
- to store paper documents relevant to inspection of test facilities and study audits in the SNAS archive and electronical documentation in AIS, in compliance with valid legislation;

- to issue methodological guidelines concerning GLP (MSA series G). their updating and publication on SNAS website – www.snas.sk;
- if a test facility/audited study does not meet GLP principles criteria, to notify OECD Secretariat, EC and through them other member states;
- to train, educate and monitor GLP inspectors;
- Organizing seminars for testing facilities focused on providing information about new regulations in the field of GLP and MSA G as needed.

6.1.2 Confidentiality of information

During inspections and study audits, inspectors have access also to confidential, commercially valuable information and documents about which they inform in detail in their reports.

Confidential information, as e. g. reports from inspections, list of findings, records from negotiations are accessible, except from the management of inspected test facility, GLP Guarantor and inspectors, only to the SNAS employee and members of GLP Committee; all these persons are bound by signing „ Statutory Declaration“ (TL 02) to discreetness as for facts found.

To ensure maximum confidentiality, each inspector/lead inspector, upon appointment and upon receipt of the test site documentation for review, signs the " Declaration of the SNAS GLP Inspector " (TL 503/G), in which he declares that he has no financial or other interests in the inspected test site, is not aware of any conflict of interest, and at the same time undertakes to maintain confidentiality regarding the facts discovered. On the Declaration, there is mentioned the name of test facility, registration number, the name and identification of the inspector and a dated signature. The Declaration is drawn up in duplicate, one passes to the test facility, the second remains in the archive of SNAS in the folder of inspected test facility.

The expert, observer and interpreter sign „ Statutory Declaration“ (TL 02), in AIS.

Common information about GLP activities or the list of test facilities holding GLP Statements are not considered confidential and are accessible on the SNAS website www.snas.sk.

6.1.3 Organizational ensuring of decision on granting / maintaining in force / renewal of the statement validity / based on the result of inspection

Based on a decision of the Director (Annex 1, ST-07), the SNAS Committee for GLP (V-SLP) is established which is a director's advisory body for decision-making on granting / refusing / renewing / suspending / revoking the GLP Certificate. The mission and scope of the GLP Committee determines its status (ST-07). Members of the Committee are appointed by the Director; the list of Committee members is attached to the ST-07.

In the Committee, written materials about individual services are discussed and assessed, mainly partial and summary reports of inspectors as well as their conclusions from inspections of test facilities as regards GLP Principles observance and also evidences how the identified non-compliances were eliminated. A recommendation for director on granting / non-granting / renewal / suspension and cancellation a GLP Principles compliance Certificate is the result of this assessment. Resolution of the Committee is adopted by voting.

A Committee member, personally interested in a discussed case (e. g. taking part in the inspection, an employee of the assessed facility, etc.) can participate in the discussion but not in voting about the case in question.

6.1.4 GLP Inspectors

As inspectors conducting inspections or study audit can be appointed:

- permanent SNAS staff members – internal inspectors;
- external inspectors taking part in an inspection on the base of contract;
- experts taking part in an inspection based on a contract.

6.1.5 Qualification requirements

- **Inspector**
  - University degree in natural science, chemistry, pharmacy, human or veterinary medicine, at least 4 years' experience in the field, knowledge of relevant national legislative related to GLP and safety assessment of chemicals as well as knowledge of relevant OECD and EU regulations.
- **Lead Inspector**
  - qualification requirements the same as for an inspector, practice in carrying out inspections as the inspector, positive monitoring.

If necessary, e. g. SNAS does not have a proper inspector of required expertise or experience for a specific test facility, a specialist can be used acting as an expert in the process of inspection.

- **Expert** (specialist)
  - University degree in relevant field and at least 5 years of experience in the field.

6.1.6 Personal requirements

The personal requirements for an inspector, lead inspector and expert include integrity, good observation skills, professional judgment, the ability to formulate conclusions

in writing and orally, the ability to make decisions, objectivity, correct behaviour, appropriate communication skills, reliability and honesty.

6.1.7 Practical preparation

- **Inspector**

Candidate for GLP inspector have to attend a basic 4-day training of GLP (ANNEX 1 of NP), then take part at least in one inspection with an observer status, and at least in 3 inspections with the status of an inspector (monitored inspector) under the guidance of the Lead inspector, which also evaluate work of inspector in monitoring.

If the candidate for inspector is an expert from a testing facility included in the national monitoring program, or an expert from ministries with GLP in their work, he/she will only complete one-day training (ANNEX 2 NP, TL 519/G), because such an expert already knows the GLP system well from practice. He/she will then complete 1 inspection with the status of observer and 1 inspection with the status of inspector in training (monitored inspector) under the guidance of a lead inspector, who will also evaluate the inspector's performance in the inspector's monitoring.

Inspector in training has to write a partial report from the inspection where he acted as a monitored inspector. The Lead inspector observes the performance of the monitored inspector from the technical and ethical point of view and after completing of inspection he evaluates his performance in AIS (Folder „Inspection Group“, Part „Monitoring“). In the event that the performance of one inspection as an inspector in training is insufficient (various specifics may occur), the lead inspector will propose the performance of additional inspections under supervision.

If the potential inspector was positively evaluated (preparation for inspection, performance of inspection, GLP knowledge including knowledge of OECD documents and national legislative, moral behaviour etc.), GLP Guarantor gives a proposal for the SNAS Commissions for Appointment of Assessors for his/her nomination as GLP inspector.

- **Lead inspector**

After having performed at least 5 further regular inspections as an inspector, the Lead inspector candidate had to conduct at least 1 inspection as a monitored Lead inspector under surveillance of an experienced Lead inspector. He/she has to write the summary report from the inspections where he acted as a monitored Lead inspector.

An experienced Lead inspector (trainer) evaluates the performance of the trained Lead inspector in the same way as the performance of a trained inspector. If the training during one inspection for the Lead inspector candidate is not sufficient (for various reasons), the Lead inspector – trainer can propose further inspections under surveillance. If the monitoring Lead inspector evaluates the trained Lead inspector as an appropriate candidate, GLP Guarantee gives a proposal for the SNAS Commissions for Appointment of Assessors for nomination as a Lead inspector.

Lead inspectors are obliged to attend a special regime of technical trainings organized by SNAS yearly or OECD in two years period (at least one Lead inspector should attend GLP OECD training courses – and he then will train other inspectors and Lead inspectors).The training also includes the mutual exchange of experience with other monitoring bodies of the Member States, participation in working group meetings, or participation in evaluations – on-site evaluation (OSE), previous Mutual Joint Visit OECD.

- **Expert** (specialist)

The expert (specialist) will complete basic training in relevant MSA/G, based on the area (e.g. IT) in which he will conduct the inspection and formulate an expert opinion.

Note: If an inspector, lead inspector, expert does not participate in a GLP inspection or training for more than 3 years, he must complete a one-day training course before the next inspection (ANNEX 2 NP, TL 519/G).

6.1.8 Nomination of Inspectors and Lead Inspectors

The SNAS Commissions for Appointment of Assessors negotiate the proposal for nomination as a GLP inspector, assesses the meeting of criteria and propose to the Director of SNAS nomination of the candidate to the position of inspector.

The inspector, after having obtained a letter of appointment (TL 36) signed by the Director of SNAS, is incorporated into the base of GLP inspectors.

Similarly, the same procedure is after meeting required criteria for promotion from the inspector to the Lead inspector.

The Lead inspector, after having obtained a letter of appointment (TL 36) signed by the Director of SNAS, is incorporated into the base of GLP Lead inspectors.

SNAS is responsible that inspections are conducted only by inspectors who met all required criteria as evidenced by the inspector's service cards issued by SNAS.

Documents on qualifications and trainings of inspectors and Lead inspectors as well as how they were assessed during trainings and inspections, are archived at the SNAS database, the database is kept in electronic form in AIS from 2016 year.

6.1.9 Duties of SNAS when monitoring inspectors' performance

Performance of inspector during each inspection is monitored by the Lead inspector. During monitoring, similar criteria are assessed like when the inspector/Lead inspector candidates are assessed including effectiveness of inspection group organizing, keeping the timetable as well as communication with test facility representatives when arising problems during inspection are solved. The performance of Lead inspector is monitored by the GLP Guarantor and GLP Committee SNAS by evaluating Summary Report from inspection and whole process of inspection documented in AIS, however, it may also

be monitored by GLP guarantor during the on-site inspection, just as inspectors are monitored by the lead inspector.

Monitoring person records findings in the monitoring of the Inspector (or expert) directly to the folder AIS/Monitoring.

Results of monitoring are reviewed by GLP Guarantor and if necessary - negative evaluation, Guarantor proposes corrective action and evaluates their effectiveness a certain time interval (at the next inspection of the monitored inspector). The records are stored in database of assessors in AIS.

The knowledge gained from monitoring is then used for improvement trainings of inspectors/Lead inspectors.

6.1.10 Identification of inspectors

Before each inspection, an inspection team is nominated and its leader appointed. The group proposal is sent to the test facility for approval. GLP inspectors of the SNAS will prove themselves during the specific inspection in the given test facility with the Service card of the GLP inspector issued by the SNAS (TL 518/G).

The Lead inspector is responsible for inspection and Summary report, the inspector is responsible for inspection of the part allocated to him and a partial report from the inspection. Lead inspector inserts own observation and information from Partial report/s of inspector/s to Summary Report.

As a Lead of the inspection group can be nominated a Lead inspector only. If further Lead inspector is a member of inspection group for inspection of a test facility, he, in this specific case, acts only as an inspector, he reports to the Lead inspector nominated for service and from such inspection drafts only a partial report.

6.1.11 Determining authority of inspectors

Inspectors/Lead inspector after having proved their identity are authorized:

- to enter the test facility and monitored premises;
- to have access to test facility's data, to test and reference substances, standard operating procedures documentation, as well as to further documentation containing procedures for checking of organizational processes and planning conditions, conducting, monitoring and recording non-clinical studies including records on electronic devices, to the source code of programme etc.
- to copy checked documents with the aim to document inspection results;
- to check devices, equipment, way of transport and further means used for conduct of studies;
- to invite external experts for evaluation of technical matters, if necessary; these persons are obliged to observe the same rules of keeping secrecy as inspectors;

- to require from checked persons trustful and complete information on activities and facts related to the inspection;
- to ask from the test facility management written information on corrective measures adopted – in AIS to each non-compliance separately before the date set up by an inspector.

If a test facility does not enable inspectors to enter into its premises or to access to objects related to the GLP inspection or holds back information, the result of such inspection will be assessed "THE TEST FACILITY DOES NOT COMPLY WITH GLP PRINCIPLES" and its Certificate is suspended. The result of inspection must be notified to the OECD Secretariat and to the EC immediately and the reason for the suspension should be clarified.

6.2 DESCRIPTION OF THE NATIONAL GLP COMPLIANCE PROGRAMME IN THE SLOVAK REPUBLIC

The aim of the Slovak National GLP Compliance Programme (hereinafter SN GLP CMP) is to verify, whether a test facility performs non-clinical studies of health and environmental safety of new items (chemical, biological origin) performed on an order of a sponsor, in compliance with GLP Principles and whether the data obtained in studies are of the required quality.

6.2.1 Preliminary provisions and SN GLP CMP Scope

SNAS assesses GLP compliance of applicant – test facilities according to relevant Slovak legislative, EU and OECD regulations.

6.2.1.1. The field of substance testing

The field of substance testing contained in:

Directive 2004/10/EC
Pharmaceutical products
Pesticide products
Cosmetic products
Veterinary drugs
Food additives
Feed additives
Industrial chemicals
Biocides
Nanomaterials (from 2013)
Medical devices (from 2020)

6.2.1.2. The field of monitoring

GLP Principles observance is defined with taking into account categories of chemicals listed in 6.2.1.1 as well as according to the types of tests carried out on them, i.e.:

- physical-chemical testing;
- toxicological studies;
- mutagenicity studies;
- eco-toxicological studies performed on water organisms as well as on organisms living on and under the surface of the earth;
- studies of behaving of substances in water, soil, in the air; bioaccumulation studies;
- studies of residues;
- studies of effects on mesocosmos and on natural ecosystems;
- analytical and clinical testing;
- another tests (e. g. tests of microbiological safety, histo-pathological assessment, tests of stability, analytical part of bioequivalence studies, safety pharmacology, pharmacokinetics, studies on safety of vaccines, etc.).

The development and validation of analytical methods, if it is necessary for the performing of the non-clinical studies can be also included as part of non-clinical study.

6.2.1.3. Inspections

Inspectors at a test facility check the level of compliance with GLP requirements when a test or tests of non-clinical study is/are performed by means of:

a. inspections including pre-inspections of a test facility or an audit of one or several studies with the aim of **issuing a GLP Certificate**;
b. inspections with the aim of **extending the GLP Certificate validity**;
c. inspections with the aim to **renew the validity of GLP Certificate**.

The audit of a study/studies is a compulsory part of every inspection in the test facility.

Special categories of inspections:

Repeated inspection – it is performed if nonconformities found during the first inspection are of such an extent that it is clear that test facility is not able to remove them within a term given by the frame of contract (maximally 2 months when renewing statement validity); such repeated inspection is invoiced separately as a new inspection.

Follow up inspection (checking of small drawbacks removal) – it serves for removal verification of several minor non compliances found during inspection. Such inspection shall be carried out on the basis of the decisions of the GLP Committee and

approval by the Director after reviewing the Summary report and presented evidences of the removal of non-compliances. Such inspection is used to ensure about the correct removal of the deficiencies identified during inspection, or if the deficiencies founded before are not repeated again.

Extraordinary inspection of a test facility or study audits on request of monitoring bodies (mentioned in the § 25 - 31 of the Act No. 67/2010 Coll. and European Regulation Authorities – EMA, ECHA EFSA). If serious non-compliances are found, the Certificate validity is immediately suspended and the organization is obliged, for a renewal of the Certificate validity, to remove non-compliances and apply for inspection at his expense. In the case of deficiencies in audited study which have influenced the results of the study, is study stated as non in compliance and failure to comply is reported to the OECD, the EU, and all Member States. It is usually carried out as part of a scheduled inspection for renewing the validity of the GLP Certificate.

Unplanned inspections shall be carried out in the case if test facility voluntarily asked for the suspension of the validity of the Certificate because no requests for GLP studies from sponsor or no activity for an extended period (reconstruction, mowing to other premises), then asks for the cancellation of the suspension, and in given year is not scheduled monitoring for re-newing validity of Certificate. An unplanned inspection can also be carried out on the basis of a serious complaint about the test facility.

6.2.1.4. GLP Certificate

The GLP Certificate (TL 58) testifies that the test facility acts in compliance with OECD GLP Principles implemented in Slovak legislation. The Certificate is issued in English on request, too. The statements/Certificates issued by monitoring bodies in other OECD accepted countries are considered equivalent.

The Certificate contains (§ 13 (10) of the Act No. 67/2010 Coll.):

a) The name of accrediting person (issuing the Certificate) and its residence;
b) Trading name and residence or the place of trading of the applicant and an identification number if was granted;
c) The object and scope with relevant non-clinical studies performed by the applicant;
d) The name and family of the person(s) who is (are) a statutory body or a member of the statutory body of the applicant together with the manner in which they act on behalf of the applicant;
e) Number of Certificate and dates of its validity;
f) Information about the conditions under which it was issued and its validity,
g) further data if necessary;

6.2.1.5. The period of the validity

The period of validity of the certificate 2 years.

For services registered in AIS before 1.9.2018 the previous mode was valid (for new test facility – validity 3 years / for renewed certificate 5 years + regular monitorings) to the end of the validity of certificates issued.

6.2.1.6. Frequency of inspections after granting Certificate

Testfacility is obliged to apply SNAS, six months before the expiry of the period of validity of the certificate, for inspection for a renewal of validity of certificate by sending application through AIS. The inspection shall be carried out usually in intervals of about 18-20 months from issuing Certificate so, in order to process and issue a new certificate with dates continuous after previous date. If test facility does not make a timely request for renewal of the certificate, SNAS cannot guarantee the continuity of validity dates of actualised Certificate.

Conducting at least one GLP study during the period of Certificate validity is the condition for renewal of its validity Otherwise, if it is found that the test facility did not perform any study within the Certificate validity period, and even for the following period showed clients no interest in the conduct of the study (not preparing new study even no negotiations with sponsor about new study in near future) the Lead inspector submits a proposal for suspension of the statement validity.

Principle of a model study (or a fictive study for biological test systems) can be used only once, usually within the first cycle of the Certificate validity (during granting or extraordinary situation, e.g. a change in the organizational structure with the exchange of key employees…).

A test facility is ranged into the SN GLP CMP, after having been granted the first Certificate.

The list of test facilities ranged into SN GLP CMP has a form of a database and it is published on the SNAS website and in the Journal of the Slovak Office of Standards, Metrology and Testing.

6.2.2 The procedure for incorporating a test facility into SN GLP CMP

6.2.2.1. Basic information

a) Basic information on the process of granting GLP Certificate can be provided by Secretariat and GLP guarantor. SNAS personnel do not provide the information, which can be considered as consultation or other consulting services, and which could cast doubt on the objectivity of the inspection process and decision making.

b) Since April 4, 2016, all processes, including the submission of application for granting GLP Certificate, the course thereof, processing of assessment outputs and clearing of the whole service are carried out electronically - directly in the Accreditation

Information Service (AIS). Annex to Application Form for granting/renewing validity and Price list of Services can be found on the SNAS website https://www.snas.sk/en

c) Before submitting the application, a new legal entity wishing to apply for GLP Certificate have to register at http://ais.snas.sk where all the instructions are given.

d) The subject wishing to apply for service (Granting/renewing validity) shall first fill/check in AIS the accuracy of data in the Client Card - the sections of Basic Data. Only than he can proceed to the completion of "Application for GLP Service" (hereinafter only Application). When submitting the Application, he will be invited to input in electronic format all prescribed documents (p. 6 of the Application). These are:

- Annex to Application where types of studies performed in test facility and types of test items are defined,
- GLP Principles or individual documents describing all GLP requirements (List of personnel, Lis of equipment, test systems, List of SOPs, Master Schedule...)
- Documents confirming the applicant's legal form,
- Document on the organizational structure of legal entity, making clear the incorporation of all sites the subject asks SNAS apply for GLP Certificate,
- Floor plan of test facility with marked GLP areas

If test facility has more test sites, each of them should be described separately (p. 4 of the Application).

e) When filling in the first Application in AIS, it is also necessary to attach the proof of payment of a fee associated with the submission, registration and assessment of the Application.

f) The application can be signed directly in AIS, in which case it is no longer necessary to deliver the application to SNAS. After signing, the service is automatically created in AIS. If the application is not signed in AIS, then the signed application must be delivered to SNAS. The procedure will only begin with the delivery of the signed application to SNAS.

g) Signing outside AIS and delivering the application can be done using one of the following options:

1. electronically - to the SNAS e-mail box via the ÚPVS website,

2. in paper form - print it out and, after signing it by the statutory representative of the organization, deliver/send it by post to the SNAS address.

The application can be viewed in pdf format or printed in AIS and also by clicking on Application details and then pressing the "Generate PDF" button.

h) The SNAS Secretariat will check the formal requirements of the application. In case of incomplete materials, SNAS will invite the applicant to supplement them. If the application meets the requirements, it will forward it to the Department of Laboratories, Inspection Bodies and GLP of SNAS.

i) Coordinator (case officer) will review the Application and if necessary, will ask to complete it. If the Application meets the requirements, gestor in co-operation with GLP Guarantor will plan performing of service.

Note: Coordinator (case officer): SNAS employee responsible for the administrative management of the service and for ensuring the proper conduct of the inspection (communication with the VI and IS members, with representatives of the entity, ensures mandate contracts, etc.).

6.2.2.2. Fee

The non-refundable administrative fee (see Price list of SNAS services RR 02) is paid only when the application is submitted for the first time (new subject) - in advance, when the application is submitted, a proof of payment is also submitted.

SNAS determines the GLP service fee according to the valid "Price list of SNAS services", published at the SNAS website (https://www.snas.sk/en). The applicant is informed about the fee amount by means of AIS. The determined amount will be invoiced to the Applicant after having finished the service, if foreign entities, payment is required in advance.

6.2.2.3. Proposal of inspection group

a) Coordinator in the cooperation with GLP Guarantor prepares „Proposal of Inspection Group" (IG). The Applicant will get by mail a notification that will enable him to access in electronic format the „Proposal of Inspection Group". Members of IG usually are: Lead Inspector, inspector/s and/or expert/s in the field of performed studies. Besides persons mentioned above, other members of inspection group can also be: observer, Lead Inspector/Inspector in training, SNAS employee entrusted with monitoring or internal audit, interpreter and eventually other persons (e.g. OECD evaluation team member, an observer from the national monitoring authority for foreign inspection, etc.).

b) The Applicant takes his stance to each IG member directly in the electronic AIS environment and by pushing the "Send Standpoint" button sends it back to SNAS. The eventual justified objections to any of IG member (i.e. competition, conflict of interest) are to be made in the electronic form. In the case of justified objections SNAS shall take this standpoint into account and prepare a new proposal. After the delivery of the consent to the Proposal, an inspection date is planned in cooperation with the subject.

6.2.2.4. Preparation of the inspection

a) Lead inspector together with Inspectors will study the documentation, which test facility inserted to the folder „Documentation", in AIS. Basic documents are: GLP

Principles (or relevant documents describing fulfilment of all points of GLP Principles, current List of SOPs and Master Schedule where all studies performed/finished in the test facility are chronologically listed. If necessary, the Lead inspector asks the test facility for additional documents (e.g. specific SOPs to audited study). The on-site inspection can start only when the applicant's documentation meets all GLP principles what decides the Lead Inspector on the basis of the opinion of the other inspectors. Usually, if documentation does not fulfil criteria, GLP Guarantor returns it to the Applicant after receiving it with Application and service will start only when documentation was revised and supplemented. Minor flaws and errors in the documentation are then discussed directly in the framework of the on-site inspection.

b) In this period, the applicant can ask for carrying out a pre-inspection for test facility asking for granting GLP certificate for the first time - inspectors get acquainted with the test facility to be inspected, check available information about the test facility, e. g. its disposition, organizational charts, some model study plans, study reports, protocols and personnel's CVs, qualification and training. Such documents provide information about:

- type, size and disposition of the test facility;
- scope of the study which inspectors will probably deal with during the inspection;
- management system of the test facility.

Pre-inspection is compulsory for foreign test facility.

c) The Lead inspector arranges with the applicant the date of the inspection and sends him electronically by means of AIS the "Program of GLP Inspection" (TL 514/G). After having got the access, the applicant will express himself in relation to the program directly in AIS.

6.2.2.5. The course of the inspection

a) The inspectors are during inspection governed by a procedure mentioned in the Decree of the Government No. 320/2010 Coll. as amended and in MSA G 03 "Inspections of Laboratories and Audits of Studies". The inspection is usually carried out on site, only in serious circumstances that prevent the on-site inspection (Covid 19 pandemic, lock-down, travel ban, state of war - decision based on risk assessment TL 601) the inspection is carried out remotely by electronic means. The method of communication will be agreed in advance and tested before the inspection (TL 604). A remote inspection may only be carried out at a test facility where at least two on-site inspections have been carried out and the national monitoring authority is fully familiar with the workplace, until the emergency situation has been resolved, the subsequent inspection will be carried out in the classic on-site manner. A new test facility must always be verified exclusively by on-site inspection.

b) At the final session, after the inspection had been completed, the Lead inspector together with the members of inspection group and representatives of the test facility discuss all findings. He shall draft a "Record on Non-Compliance with GLP Principles" (TL 504/G) which should be signed by the Lead inspector, inspector/s and the Head of the test facility. One original of the record shall be forwarded to a test facility representative and the second original Lead Inspector keeps and passes for archiving to coordinator on termination of the service. At the same time during discussion negotiates test facility´s proposal of elimination of non-compliances and dates when will be eliminated. A scan of the signed record is inserted into the Assessment Outputs in AIS.

   Lead Inspector after finishing inspection during closing meeting fills-in in electronic AIS environment /Folder Non-compliances/ all non-compliances, determines period for sending proposals of elimination and evidences about elimination and passes them to the applicant in electronic format. After the notification delivery the applicant´s representative confirms electronically in AIS environment that he was made acquainted with the noncompliance, understood it and agrees with.

   Note: If, because of justified reasons, it is not possible to fill the non-compliances and accept them in AIS electronic environment directly on site (e.g. in cases when there is no functional connection with the system, broken computer), the documented evidence is signed "Record of non-compliance with the principles of GLP". It is required to record and accept it in AIS electronic environment in the shortest possible time after the inspection with a note, what was the reason for the later insertion of data.

c) The inspector who during the test facility inspection or study audit found serious non-compliances with GLP principles, which could affect quality of the results of the monitored study or other studies performed at the test facility, is obliged without any delay to notify the GLP Guarantor of his findings together with a proposal to declassify the GLP study to non-GLP, or in the event of a large number of non-compliances affecting all studies, a proposal also immediately suspend the validity of the Certificate. Message of the non-compliance of studies with GLP principles must be immediately forwarded to the OECD and EC.

d) During final conference the Lead inspector will inform test facility management about the requirement to elaborate the draft of remedial action to each non-compliance within 10 working days in electronic AIS environment and to save them. In order to avoid later problems with the acceptance of the way of elimination, it is appropriate to discuss proposed elimination of non-compliance with a Lead inspector/Inspector (e-mail, phone) and then insert it into the AIS. In the case that inspectors have comments or do not accept the proposal (the time for elimination, not in accordance with the principles of GLP), test facility management has to rework the schedule.

e) No later than the specified deadline for the elimination of the noncompliance(ies), a description of the elimination of the relevant non-compliance with the GLP principles, together with evidence, must be entered into the AIS individually, for each non-compliance separately. The user inserts the necessary documents as evidence of elimination of the non-compliance in the detail of each one and fills in the field

"Description of correcting of non-conformities". For each non-compliance the user sends the entered information by pressing the button "Send description of correcting and evidence of removal of nonconformity" for each one separately. The responsible SNAS employees are then notified by email about the sending of the evidence. Again, it is advisable to consult the correctness of the elimination with the Lead inspector before the final submission.

f) Time period for elimination of non-compliances for first granting of GLP Certificate is not specified, it depends on possibilities of test facility. However, the service must be completed within 12 months of submission of the application so in the case of non-observance of this time period, the service will be terminated by the conclusion "NIC – not in compliance" and the certificate will not be issued. For other services, time to correct the identified non-compliances is normally within 2 months, together with evidences about elimination. Confirmation of removal in the case of renewing validity of Certificate should be received in sufficiently in advance before the expiry date of the certificate. Inspection Report can be elaborated only when all non-compliances were eliminated, then Report is submitted for discussion in the GLP-Committee SNAS and the decision of the Director, so, the date of the renewal of certificate seamlessly continued the expiry date of the previous one.

g) The Lead inspector after receiving notification from AIS about elimination of all non-compliances, together with inspectors evaluate evidences about elimination of non-compliances and comment on their removal in AIS. If he/she has reservations about the method of removal, he/she shall again contact the test facility management and request rectification. The relevant non-compliance shall be returned in AIS for completion. If the way of elimination is satisfactory If the method of rectification is satisfactory, the inspectors will produce 'Partial-Inspection Reports' which will be entered into the AIS in the Assessment Outputs. The Lead inspector will enter scans of the attendance sheet and signed statements of the inspectors there and prepare a "Summary Report" from inspection. In case of minor deficiencies in documentation, the Lead inspector can verify meeting the way of corrective actions by a requirement to submit relevant documents. If more deficiencies in the test facility activities were found, the Lead inspector can incorporate into the conclusions of the Summary Report, the proposal for subsequent (or repeated) inspection. A final decision whether follow up (or repeated) inspection will be carried out by the GLP Committee SNAS.

h) The Reports from Inspection (partial reports of inspectors and the Summary Report of the Lead inspector shall meet requirements mentioned in the Decree of the Government No. 320/2010 Coll. as amended and in MSA G-09 "Guidance for the Conduct of Laboratory Inspections and Study Audits". During inspection both inspection of test facility and study audit will be always performed.

A report from inspection has to contain at least:

- the name, address of the test facility including all test sites where audited study/ies was/were performed;

- SNAS member number/GLP Statement number = registration number;
- activity scope of the test facility;
- names of test facility management who took part in the inspection;
- names of inspectors;
- information that the inspectors announced the beginning of the inspection in advance and gave the subject for approval the inspection program and during the inspection they proved themselves with Service cards - GLP Inspector SNAS;
- location and time of performing of inspection;
- reason, object and scope of the inspection;
- summary of the inspection;
- detailed description of inspection according to points described in MSA-09;
- overall assessment together with verdict of inspectors about GLP compliance or possibly with a proposal for granting, maintenance or withdrawal of the statement by wording:
  - **"IN COMPLIANCE WITH GLP"** – not found or found only minor deviations from GLP principles (IC – In Compliance with GLP).
  - **"PEN – Pending"**(GLP compliance yet not decided on) – there were found major deficiencies, but without any effect on the integrity of the study, a follow up inspection of deficiencies removal is necessary, after the inspection, it will be definitely decided on meeting GLP principles.
  - **"NIC"** – Not in Compliance – major deficiencies found affecting the process of the study.
- information on manner of cancelling;
- dated signatures of the inspector.

i) Study audition request of Regulation Body is carried out in the same way. The Lead inspector prepares the complete report with findings from the study audit and send it to the Regulation Body and to the accrediting person (SNAS).

j) GLP Committee negotiate the summary report from inspection and check of corrective actions and recommend to the SNAS Director to grant /do not to grant the GLP Certificate and to incorporate/do not incorporate the test facility into SN GLP CMP. GLP-Committe meeting is governed by the Statute and the rules of procedure described in ST-07.

k) If the applicant met all requirements for granting the Certificate, the accrediting body grants to the applicant the Certificate. Otherwise, it notifies him of not granting the statement because he did not meet conditions mentioned in § 13 (9) Act No. 67/2010 Coll. The notification should contain reasons why the statement was not granted and it should be sent in writing.

l) The test facility is entitled to attach a Certificate of compliance with the GLP principles as evidence that the test facility carries out its activities in accordance with the GLP principles, to the Report from the non-clinical study.

m) The same procedure applies for other inspections - Application for Renewal with relevant annexes shall be submitted at the latest 6 months before the expiration of validity of GLP Certificate. The procedure is the same as described above. Test facility is obliged to insert into the AIS updated GLP Principles of the test facility (or separately relevant documents) before each inspection in the same way as it was done during first inspection.

n) The test facility must, during the validity of the certificate, comply with the conditions under which it was issued (Section 10 (3) of Act No. 67/2010 Coll.).

o) The test facility shall immediately notify the accrediting authority of any significant changes relating to the issued certificate; namely changes in the subject and scope of activities, organizational changes, changes in personnel directly related to the subject of the issued certificate, changes in ownership of the testing facility or other authorized possession of the testing facility, change of address, etc. (Section 10 (4) of Act No. 67/2010 Coll.).

6.2.3 Procedures for complaints and appeals against a result of inspection

a) The test facility management can bring complaint against the process of inspection at the Lead inspector. Problems and disputes between inspectors and test facility management are usually discussed and solved during the final session, after the inspection has been completed.

b) If the Lead inspector and the test facility management do not come to the agreement on the final formulation, the test facility management has the right to make appeal in writing against the findings of inspectors or for some operation, and the procedure, within ten days. The objections do not have dilatory effect.

c) The test facility management has to prove that inspector(s) are wrong and support it by arguments.

d) The appeal should be sent to the SNAS Director, who based on opinion of experts will decide about the legitimacy of the appeal within 60 days.

e) If the SNAS Director finds out that the appeal is justified, he ensures that the Lead inspector will respect objections of the applicant and ensures a correction. He will notify the applicant or the statement holder of the removal of the drawback in written within 3 days.

f) If the SNAS Director finds out that the objections are not justified it will notify the test facility within 3 days after the objections had been explored. The SNAS Director verdict is definitive. In case of disagreement with the verdict of director it is possible to appeal to a court.

6.2.4 Removing, withdrawal from SN GLP CMP or statement validity suspending

a) A reason for removing a test facility from the SN GLP CMP is Certificate cancelling on reasons mentioned in § 14 points 1 – 4 of the Act No. 67/2010 Coll. In such a case in the list of test facilities should be mentioned "Removed from Inspection Programme" – Certificate cancelled.

b) If a test facility does not want to be incorporated in the SN GLP CMP any more, it should notify SNAS in writing of its withdrawal and return its valid Certificate.

c) If a test facility – for any reason – cannot temporarily meet conditions under which the Certificate was granted (has for longer time any orders for GLP studies), can ask SNAS for a temporarily suspension of its Certificate from the date of delivering of the request for suspension indefinitely. Test facility has to ask for execution of extraordinary inspection in the case of acquisition of non-clinical studies, to be renewed the validity of the certificate. If SNAS during an inspection or study audit finds out not meeting the conditions under which the Certificate was granted and, according to a judgment of inspectors, this not meeting was temporary, it suspends the Certificate validity to the time when the reasons for failure to comply with the requirements are being removed.

d) Cancelling of a suspension can be done only after the surveillance was carried out. If the Test facility fails to apply for extraordinary inspection in the period of validity of the original Certificate, test facility will be permanently withdrawn from the National Program to the date of expiry of validity of the Certificate.

e) A test facility withdrawn or removed from the SN GLP CMP can ask again for incorporation according to the procedure mentioned in the section 6.2.2.

6.2.5 Publication of test facilities incorporated into SN GLP CMP

a) Each change – incorporation of a new test facility into SN GLP CMP, suspension, excluding or withdrawal is published in the list of test facilities together with the GLP Certificate on the SNAS website www.snas.sk and in Journal of the Slovak Office of Standards, Metrology and Testing.

b) SNAS because of the membership of the Slovak Republic in OECD and EU regularly informs, through its representative in GLP Working Group about incorporation/exclusion of new test facilities or the results of inspections also monitoring bodies of the OECD and EU member countries.

6.2.6 International acceptance of data

a) The study results carried out in test facilities in the SN GLP CMP can be submitted to the national regulation bodies with the aim of registration and issuing licence in all EU and OECD countries.

b) For that reason, each member country should draft a GLP report about inspections on its territory and abroad. An integral part of the report is a test facilities list where inspection was carried out, inspection dates and short summary of inspection results. This report is sent to all monitoring authorities of the countries in the OECD and EC.

c) If a test facility incorporated into SN GLP CMP has some problems with acknowledgment of its study data by foreign regulation bodies it should without any delay notify SNAS of this fact.

d) Inspection performed by SNAS in non-OECD member country (even if test facility has GLP Certificate), does not warrant that the data from the study will be automatically accepted in other Member States. Each regulatory authority has the right to send its inspectors, in order to verify the degree of compliance with GLP principles for selected study.

6.2.7 Performance coordination on the international level

a) SNAS is a national body responsible for monitoring GLP compliance of test facilities in Slovakia.

b) All requirements for a test facility inspection or study audits in Slovakia from abroad should be addressed to SNAS.

c) SNAS is also responsible for providing correct information on GLP level in individual test facilities in Slovakia.

d) Inspection shall be carried out at the request of the foreign test facility from a country which has not its own authority, if SNAS's monitoring capacities allow it.

7 RELATED FORMS

TL 58: GLP Certificate

TL 24: Satisfaction questionnaire in the field of accreditation/SLP service

TL 36: Appointment decree of the inspector/lead inspector of GLP

TL 502/G: Annex to Application

TL 503/G: Declaration of SNAS GLP inspector

TL 504/G: Record of non-compliance with GLP Principles

TL 509/G: Confirmation of participation in SNAS basic/improvement training for GLP inspectors

TL 514/G: Schedule of inspection

TL 515/G: Presence list

TL 516/G: Summary Report

TL 517/G	Partial Report from GLP inspection SLP
TL 518/G	Service card of GLP Inspector/Lead Inspector SNAS
TL 519/G	Introductory training of GLP inspector
TL 601	Risk analysis
TL 604	Agreement on the use of ICT

8 ANNEXES

Annex 1 – Basic GLP training

Annex 2 – Basic GLP training for experts using GLP in their practice

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8.1 ANNEX 1: BASIC GLP TRAINING (28 HOURS/4DAYS)

Theoretical preparation	Duration (hours)
Act 67/2010 Coll.	1
Government Regulation 320/2010 Coll. and Government Regulation No. 92/2012 Coll.	1
Directive 2004/10/EC	1
Directive 2004/9/EC	1
1981 Council Act Decision [C (81)30/Final] on the Mutual Acceptance of Data in the Assessment of Chemicals as ammended	1
1989 Council Decision Recommendation on Compliance with Principles of Good Laboratory Practice [C (89)87/Final]	1
Slovak National GLP Compliance Monitoring Programme	1
OECD Test Methods (1 – Physical-chemical properties, 2 - Effect on biotic systems, 3 – Degradation and accumulation, 4 – Health effects, 5 – Other test guidelines)	1
Regulation of the European Parliament and of the Council (EC) No 1907/2006 concerning the registration, evaluation, authorisation and resrtriction of chemicals (REACH)	1
Council Regulation (EC) No. 440/2008 –Test Methods	1
Current MSA G/01 – G/XX	14
Other, as needed: e.g. - *Work in AIS;* - *Specifics of inspection in individual test facilities (analytical, toxicological, ecotoxicological, histopathological and other studies);* - *Specification and requirements for animals used in GLP studies;* - *European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific purposes, [Strasbourg, 18.03.1986];* - *Government Regulation 377/2012 Coll. - requirements for the protection of animals used for scientific purposes;* - *Alternative methods in toxicology;* - *Routine, short-term, multicenter studies - differences in organization, plans, reports;* - *Criteria for selecting studies for audit.*	2
Knowledge testing and solving model questions	2

8.2 ANNEX 2: BASIC GLP TRAINING FOR EXPERTS USING GLP IN THEIR PRACTICE (8 HOURS)

Theoretical preparation	Duration (hours)
Act 67/2010 Coll.	0,5
Government Regulation 320/2010 Coll. and Government Regulation No. 92/2012 Coll.	0,5
Slovak National GLP Compliance Monitoring Programme	1
Current MSA G/01 – G/XX	2
Other, as needed: e.g. - *Work in AIS;* - *Specifics of inspection in individual test facilities (analytical, toxicological, ecotoxicological, histopathological and other studies);* - *Specification and requirements for animals used in GLP studies;* - *European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific purposes, [Strasbourg, 18.03.1986];* - *Government Regulation 377/2012 Coll. - requirements for the protection of animals used for scientific purposes;* - *Routine, short-term, multicenter studies - differences in organization, plans, reports;* - *Criteria for selecting studies for audit.*	2
Knowledge testing and solving model questions	2